Reproductive Care Center

Informed Consent for Intracytoplasmic Sperm Injection (ICSI)

INFORMATION: Injection of a single sperm into the oocyte (or egg) may be used to increase the chance of fertilization for couples that suffer from male-factor infertility or egg fertilization defects. It is recommended when couples are using frozen eggs, or are using sperm sorted using MicroSort technology for gender selection. ICSI is also usually recommended when preimplantation genetic diagnosis (PGD) testing is being done in order to minimize contamination from any extra DNA from other sperm that may be attached to the outside of the egg and subsequent embryo.

To overcome problems associated with fertilization, a single sperm is selected and injected directly inside an individual egg (Intracytoplasmic Sperm Injection, or "ICSI"). If viable sperm are available, the pregnancy rates are usually unaffected by the semen characteristics and sperm quality. ICSI can be performed in men without sperm in the ejaculate (azoospermia), if sperm can be harvested from the epididymis (collection system near the testicle) or the testicle (TESE).

Some studies have indicated an increase in the risk of sex chromosome abnormalities in ICSI pregnancies. The incidence of congenital birth defects may also be higher with ICSI, but it is unclear if this is due to the procedure itself, or to inherent problems with the sperm. It is well known that men with suboptimal semen parameters have a higher frequency of chromosomal abnormalities such as Klinefelters syndrome. Chromosome rearrangements and structural abnormalities may occur in up to 1% of pregnancies conceived after ICSI. Microdeletions of the AZF region of the Y chromosome have been found in up to 15% of men with low sperm counts. These microdeletions can be passed on to any male embryos that result. Men with low semen parameters are also more likely to have one of several cystic fibrosis gene mutations. We are aware that RCC recommends that men with low sperm counts be tested for the above mentioned abnormalities (such as karyotype or chromosome analysis, Y microdeletion assay, and Cystic Fibrosis mutation screening). If abnormalities are detected, genetic counseling is recommended. Genetic testing prior to embryo transfer (preimplantation genetic diagnosis), chorionic villi sampling or amniocentesis may be appropriate.

Some studies suggest there is an increased risk of identical twinning after ICSI, including situations where the fetuses are in the same fluid filled sac. When the fetuses are in the same sac (monochorionic and monoamnionic) there is an increased risk for miscarriage and late in pregnancy complications such as twin-twin transfusion can occur. Fortunately, this occurs in less that <2% of the cases after ICSI with embryo transfer at the cleavage stage. The expected rate after natural conception is <0.4%.

The potential advantages of selecting ICSI include: (1) enhancement of the fertilization rate thereby increasing the number of fertilized eggs available for transfer into the uterus or for freezing, (2) fertilization of eggs when the chance for successful fertilization under normal insemination protocols is anticipated to be low and (3) minimizing the likelihood of not getting any eggs to fertilize when the semen parameters are marginally abnormal. It is also possible that none of the eggs will fertilize, even with ICSI.

The potential disadvantages of ICSI include: (1) potential for unknown risks to the egg or embryo, (2) the process of ICSI itself may damage embryos or it may degenerate the egg immediately. If you or any of your offspring should require any medical treatment as a result of physical injury thought to arise from your use of ICSI, financial responsibility for such care will be yours.

Potential alternatives to the use of ICSI include: (1) trying basic in vitro fertilization (without the use of ICSI) with the possibility that very few and perhaps none of the eggs will fertilize, (2) use donor sperm from an approved sperm bank to fertilize the eggs or, (3) the couple could choose adoption or child-free living. Couples can also choose to not use frozen eggs, MicroSort sorted sperm or PGD.

CONSENT: We understand that ICSI involves an extra procedure fee in addition to charges associated with in vitro fertilization (IVF). We, the undersigned husband and wife, have decided to participate in the IVF program at the

Wife's Initials ____ / Husband's Initials ____

Reproductive Care Center. We have read and understand the above and all our questions about ICSI have been answered. We have been encouraged to ask further questions at any time if doubts about our participation arise.

We acknowledge that neither the RCC, nor the physicians or staff have made any warranties with respect to: (1) the viability or successful fertilization of eggs after ICSI, (2) the establishment of pregnancy as the result of this treatment, (3) the lack of risk of a birth defect, miscarriage, tubal and/or ectopic pregnancy, multiple pregnancy or complication after embryo placement in the uterus.

We acknowledge the receipt of a copy of this agreement and agree by placing our initials next to the selection below as the method to be employed during IVF. We understand that we can change the options below with each subsequent IVF cycle if desired. This consent will remain in effect for 5 years from the date of signing or for up to 12 IVF cycles unless a new consent is signed by the couple and delivered to and acknowledged by RCC staff.

ICSI Preference

_____ We desire ICSI to be performed on all of our eggs that are sufficiently mature and will pay for this in advance. This option is required when a couple is using frozen eggs, sperm sorted using MicroSort technology, or are using PGD for specific gene abnormalities when PCR is used.

_____ We desire ICSI to be performed on approximately 50% of our eggs that are sufficiently mature and will pay for this in advance. We desire that attempts be made to fertilize any remaining eggs using conventional IVF techniques. We acknowledge that there is no discount on the ICSI procedure in this situation due to the work involved.

_____ If we have chosen to not initially use ICSI despite the fact that it has been recommended due to the semen parameters, we desire that "rescue ICSI" be performed the day after egg retrieval if none of the eggs fertilize with normal IVF. We realize this has a much lower fertilization rate than ICSI on the day of the egg retrieval, but is occasionally successful in achieving a pregnancy. If rescue ICSI is done, we agree to pay the standard fees at the time of the procedure.

_____ We realize the sperm quality is borderline, and will pay for ICSI if the lab decides it is recommended based on the sperm collected the day of egg retrieval. If IVF is still recommended by the lab but no fertilization occurs, we desire rescue ICSI as described above. If ICSI is done, we agree to pay the standard fees at the time of the procedure.

_____ We understand that the sperm quality is considered adequate for IVF and that good fertilization (approximately 60-70% of the eggs fertilize on average) is anticipated. If no fertilization occurs (2-3% of cases with normal appearing sperm), we desire rescue ICSI as described above.

_____ We do not want ICSI to be done under any circumstances.

Donor Sperm Backup Preference

We understand that despite the expectation, there may be a failure to obtain adequate sperm from the husband for ICSI. Even if sperm is obtained it may be immotile which makes it difficult to determine if it is viable. We acknowledge that even if ICSI is performed, fertilization may not occur. If no sperm are obtained and ICSI was planned, we:

_____ desire to use donor sperm, if available. We acknowledge that it is our responsibility to order and have delivered to Reproductive Care Center any donor sperm desired. We understand that only sperm from an approved sperm bank may be used. Donor sperm must be delivered to RCC prior to egg retrieval.

_____ do not desire to use donor sperm. We understand that in this case any eggs retrieved would not be able to be used and would be discarded.

Genetic Testing Preference

_____ We desire and will ensure prior to proceeding with the treatment cycle that the husband have appropriate testing to include a chromosome analysis, Y microdeletion assay, and Cystic Fibrosis mutation screening. This is recommended for men whose sperm concentrations are less than 10 million/ml including when no sperm is in the ejaculate (azoospermia).

_____ We are aware of the risks but only desire the following test(s) on the husband which we will have completed prior to proceeding with the treatment cycle:
- □ chromosome analysis
- □ Y microdeletion assay
- □ Cystic Fibrosis mutation screening (recommended in all Caucasian couples attempting pregnancy)

_____ We are aware of the risks and do not desire testing on the husband for chromosome analysis, Y microdeletion assay, or Cystic Fibrosis mutation screening.

_____ Not applicable as the semen parameters are considered normal but we are using frozen eggs, MicroSort sorted sperm or we desire PGD.

We understand that payment for ICSI is an additional fee in addition to the basic IVF fees. We agree to pay this fee in advance if this is selected or on the day the ICSI is performed if it is determined to be indicated.

_____	_____
Husband's Signature	Date
_____	_____
Witness to Husband's Signature	Date
_____	_____
Wife's Signature	Date
_____	_____
Witness to Wife's Signature	Date